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I have no relevant conflicts of interest to disclose.

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Postprostatectomy Incontinence and Pelvic Floor Muscle Training: A Defining Problem

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Urinary incontinence is a common complication of radical prostatectomy, regardless of the technique used [1]. This complication has a particularly negative impact on quality of life for the men who are affected by it, so any intervention that minimizes its incidence is worth considering. In this issue of *European Urology*, Geraerts and colleagues [2] report the results of a randomized clinical trial comparing combined preoperative and postoperative pelvic floor muscle training (PFMT) with postoperative PFMT alone. They basically found no differences in continence rates between the two approaches and conclude that the addition of preoperative PFMT is no better than standard postoperative continence rehabilitation with PFMT. In contrast, Centemero et al [3] conducted a very similar randomized clinical trial and reported improved early continence with the addition of preoperative PFMT. The effect size noted in the second study was marked,

with the risk of incontinence being reduced 41% at 1 mo and 38% at 3 mo. Effectively, these two studies are almost identical and yet report quite conflicting results.

How do we explain this discrepancy? Simply put, it is all in the choice and definition of the outcome. Geraerts et al [2] define *continence* as three consecutive days of 0-g urine loss on a 24-h pad test. Using this high standard, 98% of the participants in the experimental group and 95% in the control group reported urinary continence at 1 yr. This result is particularly impressive given that the authors report that 28% of patients in the experimental group and 34% of patients in the control group were incontinent preoperatively, presumably using the same definition.

While I suppose it may be possible that radical prostatectomy is a novel treatment of incontinence, this possibility strikes me as highly unlikely. Rather, I suspect that the definition of *incontinence* used in the study itself was problematic. Although pad tests are thought to be objective, patients may change their activity level or make other behavioral alterations to prevent leakage. These changes, in turn, may influence the results of the pad test. One could see patients in the postoperative period adjusting their activities to cope with changes in urinary control.

While they might then be considered dry using the pad test, we should ask if they are truly continent, given that they may have been forced to change their daily routines and limit their activities.

Centemero et al [3] used a different primary outcome in their study that may explain why they found an advantage to the addition of preoperative PFMT. They defined *continence* as no urinary leakage reported in a patient-completed bladder diary coupled with an in-office negative stress test. In contrast to Geraerts et al [2], who report 3-mo postoperative continence rates of 73.3% and 70.9% in the experimental and control groups, respectively, Centemero and colleagues [3] report 3-mo postoperative continence rates of 59.3% and 37.3%, respectively. While

considerably worse, these rates are more reflective of rates from prior large multicenter studies [1], supporting the validity of the results. This characteristic may be because the definition used by Centemero et al [3] incorporated an element of patient perception in the outcome assessment that many might consider somewhat subjective but that also might make the end point more relevant to the clinical scenario. Which is the “better” way to define *incontinence* after radical prostatectomy? The answer is unclear. What is clear is that the choice of end point affects the results of the study.

It is interesting to consider that both studies included disease-specific health-related quality of life (HRQOL) as a secondary outcome. Geraerts et al [2] used the incontinence impact score of the King’s Health Questionnaire, while Centemero et al [3] used the International Continence Society male short form to assess disease-specific HRQOL. Both studies showed a significant HRQOL advantage with the addition of preoperative PFMT. Some might argue that the use of HRQOL as a primary end point is problematic because it is too subjective and likely incorporates many other factors beyond just the physiologic contributors to urinary continence. I would contend that using HRQOL as a primary outcome would result in studies that better reflect the clinical scenario that patients face and ultimately would inform decision making at the bedside to a much greater degree.

The issue of the optimal way to define *postoperative urinary incontinence* goes beyond the question of whether the addition of preoperative PFMT improves outcomes. The uncertainty regarding the best way to define *postprostatectomy incontinence* effectively makes it nearly impossible to determine if PFMT *at any time point* is effective in improving this outcome. A recent report from the Cochrane Collaboration [4] systematically reviewed the literature on conservative management of postprostatectomy urinary incontinence and identified 12 studies

that included PFMT to “prevent” urinary incontinence in at least one arm. The authors made the important distinction of separately analyzing studies of men who were incontinent after surgery and then sought treatment and studies in which all patients undergoing surgery were included in an effort to “prevent” incontinence. In the setting of prevention, the authors concluded that there is no clear support that conservative management of any type is helpful for postprostatectomy urinary incontinence. They specifically note that definitions and measurements of outcomes varied across studies and implied that this factor hampered their ability to draw meaningful conclusions. In fact, they stated that the primary outcome measure of future studies “should be the participant’s self-reported urinary incontinence or its effects on his quality of life” [4].

If the Cochrane Collaboration report is correct and PFMT is of little or no benefit in the prevention of postprostatectomy incontinence, what are we to do? Despite rosy reports from single academic centers and high-volume surgeons [5,6], large multicenter studies [1] from the community using patient-reported outcomes indicate that urinary incontinence is still a relatively common occurrence after radical prostatectomy. We recently reported functional outcomes ≤ 15 yr after surgery in the Prostate Cancer Outcomes Study, a population-based study of men diagnosed with prostate cancer in 1994–1995 in three states and three metropolitan areas in the United States. Participants reported incontinence rates (defined as patient report of “frequent leak or no urinary control whatsoever”) of 9.6%, 13.4%, and 18.3% at 2, 5, and 15 yr after surgery, respectively [1]. How can we help our patients avoid this bothersome complication? I believe that this is a situation in which primary prevention through increased use of active surveillance in appropriate patients, coupled with selective application of aggressive interventions in patients with worse prognostic variables, is the optimal strategy.

In 2013, there is little debate that prostate-specific antigen (PSA) screening has led to overdiagnosis and overtreatment of many cancers that would otherwise have gone undetected throughout the patient's life and, therefore, would have been clinically meaningless. The remaining controversy primarily revolves around the extent of overdiagnosis (which has been estimated to vary between 23% and 42% [7]) and the optimal way to identify these patients. Acknowledging that we need better biomarkers to identify clinically indolent disease, numerous publications now illustrate the safety and feasibility of active surveillance (which consists of serial PSA monitoring coupled with repeat prostate biopsies and dictates that aggressive therapy be reserved for patients who show biochemical or pathologic evidence of more aggressive disease) in men with low-risk prostate cancer [8,9]. Opponents of active surveillance will warn of missed opportunities to cure aggressive cancers that were mistakenly thought to be indolent at diagnosis. Studies have shown, however, that patients who progress on active surveillance are usually identified early and have similar pathologic outcomes to matched controls who undergo immediate surgery [10]. More important, patients who remain on active surveillance and do not progress are spared the adverse effects of aggressive intervention. If we prevent the urinary incontinence from occurring in the first place, defining *postoperative incontinence* and determining whether PFMT is of value in treating it become less important.

Conflicts of interest

The author has nothing to disclose.

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